Board of Health Secure Medicine Return Subcommittee: Policy decisions as of 02/19/13

Executive Summary:

The Subcommittee recommends a Board of Health Rule and Regulation establishing an industry-funded product stewardship model for medicine take-back in King County. This model would require drug producers to fund and operate the residential medicine take-back system, working with other stakeholders such as pharmacies and law enforcement. King County government's role is to oversee the take-back system to ensure its safety and effectiveness.

The Rule & Regulation will define:

1. medicines accepted for return;
2. who can use the medicine take-back system;
3. collection system requirements;
4. how drug producers work together to provide the system;
5. who the drug producers are;
6. cost responsibilities for drug producers and other stakeholders;
7. education and promotion requirements;
8. requirements for final disposal of collected medicines; and
9. local agency responsibilities for oversight, enforcement, and related processes.

Summary of Policy Recommendations:

1. Definition of "covered drugs" - medicines to be accepted by the medicine take-back system

Covered drugs are:

- Prescription and over-the-counter drugs from residential sources. Both brand name and generic, sold in any form, including controlled substances; and
- Prescription drugs for pets that are used in the home.

Exemptions:

- Drugs that have an established take-back system provided by the drug producer in place as mandated by the FDA;
- Drugs that are biological products if the producer already provides a take-back program;
- Over-the-counter drugs that are also regulated as cosmetics under the federal Food, Drug, and Cosmetics Act. Examples of these include: sunscreens, toothpastes, and antiperspirants; also pet pesticide products like flea collars; and
- Vitamins and supplements, herbal-based remedies and homeopathic drugs, products, or remedies.

2. Definition of "covered entities" - who can use the medicine take-back system

Entities that can use the take-back program to return "covered drugs" include:

- Residents of King County, including single and multiple family residences; and

- All non- business source entities that do not have an existing regulatory requirement for disposal of waste medicines.

"Covered entities" do not include business generators of pharmaceutical waste, such as:

- Hospitals, clinics, doctor's offices, veterinarian clinics;
- Pharmacies;
- Airport security and law enforcement drug seizures; or
- Other nonresidential or business sources of pharmaceutical waste as determined by the Department.

3. Definition of the collection system - methods and requirements

Primary collection methods for "covered drugs" will be:

- Pharmacy drop-off; and
- Law enforcement drop-off.

Secondary collection methods to be used as exceptions or ways to overcome specific barriers:

- Collection events; and
- Mail-back.

Collectors will participate voluntarily.

The medicine take-back system must be operated in compliance with all applicable federal and state laws and regulations.

- Current DEA regulations allow only law enforcement to take-back controlled substances, either through ongoing drop-off programs or take-back events. DEA's proposed rule to implement the Secure & Responsible Drug Disposal Act of 2010 would also allow authorized retail pharmacy drop-off programs and mail-back programs to accept controlled substances.

Operational practice protocols for medicine take-back that are approved by the DEA and Washington State Board of Pharmacy must be used as the standard approach.

In addition, protocols will:

- encourage processes that are as simple and efficient as possible for consumers and collectors; and
- encourage separation of packaging from loose pills where feasible, and encourage the recycling of packaging where feasible.

The "convenience standard" defining the level of service provided by the collection system will:

- Allow participation of all pharmacies and law enforcement agencies that want to participate as voluntary collection locations, with an alternative standard that comes into effect to ensure adequate access to residents if necessary;

- Include provisions that consider population and geography to ensure all residents have reasonable access, whether in more isolated areas or more dense urban areas; these provisions could consider distance or travel time to a take-back location as part of the standard;
- Include provisions to ensure service equity to lower income and historically underserved populations throughout the county; and
- Allow for Department discretion and flexibility in applying these standards given that collectors are allowed to participate voluntarily.

4. How drug producers work together

All drug producers will work together in a single "standard" stewardship plan unless a producer, or group of producers, opts out to form an "independent" plan.

Both the standard plan and any independent plan(s) are:

- Subject to review;
- Required to collect all covered drugs, not just those from a single company; and
- Required to meet all the provisions of the Rule & Regulation.

Criteria and standards will be defined for approval of an independent plan, including assessment of the impact on the system as a whole.

The Subcommittee's intent is that the medicine take-back system, whether provided by one stewardship plan or multiple plans, appears seamless to residents.

The drug producers are tasked with developing the methodology for apportionment of costs among drug producers working together on a stewardship plan.

The Subcommittee will hold further discussion on whether to include provisions for the following: (a) defining a timeline for an agreement to be formed among drug producers on how costs will be apportioned, with ability for the Department to impose an agreement only if producers cannot reach an agreement; and (b) defining an appeals process to be conducted by the Department if a drug producer(s) claims the cost apportionment methodology is unfair.

5. Definition of "drug producers"

The technical definition of "drug producer" is still under development, but the intention is to appropriately identify the brand owners and/or manufacturers of the "covered drugs" being collected by the program.

Compounding pharmacists preparing drugs for individual patients are not considered "producers."

Drug retail brand holders will not be considered "producers" unless it is not possible to identify the manufacturer - then the retail brand holder will be considered a "producer" and required to participate in funding the take-back program.

6. Costs for which drug producers and other stakeholders are responsible

Drug producers are responsible for the following costs:

- Secure collection boxes, any special packaging, any special security seals or tracking labels, and pre-paid mailers at collection sites.
    - Subcommittee members expressed an interest in agency assistance with the start-up cost of secure drop boxes, to incentivize participation by the largest possible number of pharmacy and law enforcement collectors.
- Transportation and final disposal.
- Programmatic costs of operating the take-back system, including administration, education/promotion, and evaluation.

The Rule & Regulation shall specify that noperson or producer may impose a visible fee on consumers when covered drugs are purchased or returned.

Staff time at collection sites shall be provided in-kind by voluntary collectors.

The Local Hazardous Waste Management Program in King County will be responsible for certain education and promotion functions, see Education & Promotion Requirements, which will be covered by LHWMP as a shared responsibility.

Local governments in the county will be encouraged to promote the use of the program through their normal communication methods with residents, see Education & Promotion Requirements.

The Department shall use cost recovery mechanisms as much as possible for its oversight costs..

7. Education & Promotion Requirements

Producers must:

- Promote safe storage of medicines and how to use the take-back program to consumers, pharmacists, retailers, and health care professionals so that collection options are widely understood by customers, pharmacists, retailers of covered products, and health care practitioners;
- Provide materials to pharmacies, health care facilities, and others;
- Provide a website and a toll-free number;
- Stewardship program(s) must evaluate the effectiveness of its education efforts as part of their annual report; and
- Stewardship program(s) must conduct a survey of residents to measure awareness and program convenience once after the first year, and again at years five and nine.

All pharmacies and collection sites should be encouraged to:

- Inform consumers about the take-back program and proper disposal of medicines; and
- Provide clear, standardized instructions for residents on drop boxes. The design of drop boxes is up to producers and collectors.

Health care providers and all other healthcare entities that are prescribing and dispensing drugs in the County should be encouraged to advise patients on availability of the take-back program, including providing materials.

Government entities in the County responsible for solid waste disposal should be encouraged to provide education about the take-back program through their regular communication methods with residents, including website materials that link to the producer-provided website(s).

Education responsibilities assigned to the Local Hazardous Waste Management Program:

- May develop guidance to producers and pharmacies on drop box instructions;
- Shall develop template educational materials for use by pharmacies, collection sites, health care providers and local governments in the county;
- Shall provide targeted education to key populations as informed by survey results and other indicators;
- Costs for these education and promotion functions will be covered by the LHWMP as a shared responsibility for the program on an ongoing basis;

8. Requirements for Final Disposal of Collected Medicines

Disposal of collected medicines must occur at a properly permitted hazardous waste facility or a properly permitted solid waste incineration facility meeting the EPA's large municipal waste combustor (LMWC) standards.

It is prohibited to dispose of collected medicines through a solid waste landfill or to the sewer. The use of smaller or lower temperature combustion facilities, such as lumberyards and cement kilns, is also prohibited for collected medicines.

Take-back programs may petition the Department to use a disposal technology that provides superior environmental and human health protection, or that provide equivalent protection at lower cost, to disposal at a hazardous waste facility or a large municipal waste combustor.

9. Local agency responsibilities

Oversight.

1) Stewardship plan review: Review submitted stewardship plans for compliance with the regulation's requirements. Solicit and consider public comments as part of plan review. Approve or reject plan(s) as appropriate. Review plan updates as required under the regulation.
2) Assess producer compliance: Determine through various means if any pharmaceutical producers covered by the regulation are non-compliant.
3) Monitor stewardship program(s): Monitor implementation of stewardship plan(s) and inspect some collection sites or transfer facilities if needed to ensure that protocols in the approved plan(s) are being followed. Review annual reports from approved take-back programs and approve any minor changes in plan(s) as operations dictate.

Fees. Fees will be collected from producers and based on the cost to provide said services – plan review, oversight activities, enforcement actions if plan non-compliant – similar to other environmental health program services and fees.

Enforcement. Receive complaints or referrals from oversight function. For non-compliant drug producers or any other non-compliant entities subject to the regulation, send warning letters and assess monetary penalties per provisions in the regulation. Amend, suspend or cancel approval of stewardship plan if noncompliance is not remedied, or if necessary to protect public health.

Enforcement actions and penalties. The Subcommittee is exploring the option of defining a penalty up. One approach is to set an enforcement penalty against a non-participating producer that is commensurate with the producer's share of the program costs if it were participating. The subcommittee appreciated this frame and also expressed a need to establish appeal processes. Staff work continues on this subject.

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